REMARKS

Claims 55-58 are pending and are rejected under 35 U.S.C. § 112, first paragraph. Applicants address each basis for rejection as follows.

Claim amendments

New claims 59-62 have been added. Support for claims 59-61 is found, for example, at page 41, lines 14-21, of the specification as filed. Support for new claim 62 is found, for example, at page 21, lines 17-23, and page 48, lines 24-26, of the specification as filed. No new matter has been added by the present amendment.

Priority documents

Enclosed herewith are certified copies of German patent application serial number 101 36 009.6, filed July 24, 2001 and German patent application serial number 102 10 425.5, filed March 9, 2002. In addition, enclosed is an English language translation of PCT/DE02/02699, filed July 23, 2002. The present application claims benefit of the filing dates of German patent application serial numbers 101 36 009.6 and 102 10 425.5 and international application number PCT/DE02/02699.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 55-58 are rejected under 35 U.S.C. § 112, first paragraph, for an asserted

lack of written description in the application as filed. In particular, the Office asserts that the specification fails to adequately describe the genus of test compounds encompassed by claims 55-58 and states (page 4):

> The genus of test compound encompasses any compound that specifically binds to the polypeptide comprising the sequence of SEQ ID NO:6 and induces apoptosis of a cell expressing the polypeptide. This encompasses an enormous number of compounds encompassing proteins, carbohydrates, lipids, nucleic acids and small organic and inorganic molecules, only one of which is identified in the instant specification. One species of test compounds, an antibody, does not sufficiently describe the genus of test compounds and does not meet the standard set forth in Lilly.

Applicants respectfully traverse this basis for rejection.

Claim 55 is set forth below. Claims 56-58 and new claims 59-62 depend from claim 55.

> 55. A method of identifying a candidate therapeutic compound, said method comprising the steps of (a) contacting a cell expressing a polypeptide comprising the amino acid sequence of SEQ ID NO:6, or a fragment thereof comprising amino acids 469-518 of SEQ ID NO:6 or amino acids 739-748 of SEQ ID NO:6, with a test compound, wherein said test compound specifically binds to the polypeptide comprising the sequence of SEQ ID NO:6, or the fragment comprising amino acids 469-518 of SEQ ID NO:6 or amino acids 739-748 of SEQ ID NO:6; and (b) determining whether said test compound induces apoptosis of said cell and not of a control cell contacted with said test compound, wherein a test compound that induces apoptosis of said cell and not of said control cell is a candidate therapeutic compound.

The standard for adequate written description is whether the description clearly allows persons of ordinary skill in the art to recognize that one has invented what is claimed (see, e.g., M.P.E.P. (Eighth Edition, Rev. 5, August 2006) § 2163.02). In

applying this standard, the Federal Circuit has held:

> If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met. *In re Alton*, 76 F.3d 1168, 1177, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996).

Moreover, in *Falkner v. Inglis*, 448 F.3d 1357, 79 U.S.P.Q.2d 1001 (Fed. Cir. 2006), the Federal Circuit stated:

> [W]e hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences. (Emphasis added.)

Falkner, 79 U.S.P.Q.2d at 1008.

Applicants submit that the specification as filed provides an adequate description of test compounds for one skilled in the art to recognize that Applicants were in possession of the genus of such compounds at the time the application was filed.

Applicants note that the specification as filed teaches:

> In general, compounds that alter a biological activity of the novel isoform of CFR-1 described herein are identified from large libraries of both natural products, synthetic (or semi-synthetic) extracts or chemical libraries, according to methods known in the art. (Page 41, lines 14-16)
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> * * *
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> Synthetic compound libraries are commercially available from, for example, Brandon Associates (Merrimack, NH) and Aldrich Chemical (Milwaukee, WI). (Page 41, line 30, to page 42, line 2)
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> * * *
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> Alternatively, libraries of natural compounds in the form of bacterial, fungal, plant, and animal extracts are commercially available from a number of sources, including, but not limited to, Biotics (Sussex, UK), Xenova (Slough, UK), Harbor Branch Oceangraphics Institute (Ft. Pierce, FL), and

> PharmaMar, U.S.A. (Cambridge, MA). In addition, natural and synthetically produced libraries are produced, if desired, according to methods known in the art (e.g., by combinatorial chemistry methods or standard extraction and fractionation methods). (Page 42, lines 3-9)

As described in the application, libraries of test compounds were known in the art at the time the application was filed. Also, as stated in the specification at page 41, lines 22-23, "[t]hose skilled in the art will understand that the precise source of the test extracts or compounds is not critical to the screening procedure(s) of the invention." Given that libraries of test compounds were known in the art at the time of filing and were readily available from commercial sources, Applicants submit that the present situation is analogous to *Falkner* where the Federal Circuit stated that written description requirement does not require the recitation of known genes and sequences. Like the genes and nucleotide sequences in *Falkner*, the genus of test compounds recited in the present claims was readily available at the time of filing.

Moreover, the specification describes several assays that may be used to determine whether a test compound induces apoptosis in a cell as required by the claimed methods. For example, at page 48, lines 6-22, the specification describes a cell-death ELISA assay and at page 48, line 23, to page 49, line 13, the specification describes *in vivo* assays in nude mice to determine the effect of test compounds on tumor growth.

In sum, Applicants submit that the specification as filed provides an adequate written description of the test compounds recited in claim 55 and its dependent claims. The specification describes what is meant by test compound,

provides numerous examples of sources of test compounds, indicates that such compounds are commercially available, and describes assays for screening the test compounds. One skilled in the art would recognize that Applicants were in possession of the genus of test compounds encompassed by the present claims. The written description rejection of claims 55-58 should be withdrawn.

CONCLUSION

Applicants submit that the application is now in condition for allowance, and this action is hereby respectfully requested.

Enclosed is a Petition to extend the period for replying to the final Office action for two (2) months, to and including August 21, 2007, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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